

Application No.: 10/616,305

REMARKS

I. Introduction

In response to the Office Action dated January 11, 2005, Applicants have canceled claims 7 and 17, without prejudice or disclaimer. Also, Applicants have amended claims 3, 11 and 13 so as to further clarify the claimed invention and to address the pending objections. Support for this amendment can be found, for example, in Figs. 1 and 2, and their corresponding sections of the specification. No new matter has been added.

For the reasons set forth below, Applicants respectfully submit that all pending claims are patentable over the cited prior art references.

II. Claim Objection

With respect to claim 5, this claim is objected to because the Examiner asserts that it is unclear what the intended scope of the claim phrase "... left position or right position" However, as expressly disclosed at page 31, lines 5-14 of the specification, the second base plate 24 is provided with one or two second extension portions 240 symmetrically extending, from both width ends of the second base plate, to the *left side* and/or *right side* (i.e., left position and/or right position) of the second base plate in the *length* direction thereof; namely, with respect to the centerline on the second base plate in its length direction. In other words, the second base plate 24 has a second extension portion extending outwardly in the length direction thereof from a position corresponding to a length edge of the first base plate (see, also, page 31, lines 15-26 of the specification).

With respect to claim 8, this claim is objected to because it is not clear how the position of the segmental portion can discriminate the specific substrate. However, as readily disclosed at

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page 8, lines 3-10 of the specification, the specific substrate in the biosensor is discriminated by the one of the plurality of second electric connection terminals to which the other of the first and the second leads is connected. As a result, a single measuring apparatus can be adapted for measuring different biosensors comprising specific or different substrates without causing an operational error.

With respect to claim 13, this claim has been amended in the manner suggested by the Examiner. For all of the foregoing reasons, it is respectfully requested that the claim objections to claims 5, 8 and 13 be withdrawn.

III. The Rejection Of Claims 1-6, 8-10 and 12-16 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-6, 8-10 and 12-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner asserts that it is unclear whether the claim limitation "... has at least a part of said first or second lead exposed to outside" requires "the lead to be disposed and exposed to the outside on the extension portion or simply somewhere on the base plate."

However, as readily disclosed in Fig. 2A of the Applicants' drawings, on the surface of the first base plate 22, the electrically conductive working electrode 23 and the lead 230 connected to the working electrode are formed such that a part of the lead 230 formed on the first extension portion 220 not covered by any part of the biosensor 2 is exposed to outside (e.g., the first extension portion 220 of the lead 230 is neither covered by the second base plate 24 nor the space member 26) (see, e.g., page 18, line 22 to page 19, line 3 and page 29, line 22 to page 30, line 4 of the specification). Similarly, on the surface of the back side of the second base plate 24,

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the electrically conductive counter electrode 25 and the lead 250 connected to the counter electrode 25 are formed such that a part of the lead 250 formed on the second extension portions 240 not covered by any part of the biosensor 2 is exposed to the outside (e.g., the second extension portion 240 of the lead 250 is neither covered by the first base plate 22 nor the space member 26) (see, e.g., page 20, lines 3-16 and page 27, line 11 to page 28, line 14 of the specification). As such, the exposed portion of the first or second lead is not just simply located "somewhere" on the base plate as set forth in the pending rejection, but is readily understandable by those of skill in the art when read in light of the specification. For all of the foregoing reasons, it is respectfully submitted that the rejected claims are in compliance with the requirements of 35 U.S.C. § 112, second paragraph.

IV. The Rejection Of Claims 3-10 and 17 Under 35 U.S.C. § 112, Second Paragraph

Claims 3-10 and 17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner asserts that the claim terms "common part" and "non-common part" are indefinite. The Examiner also asserts that a plastic plate could be referred to as a "common part," while a gold or platinum electrode could be referred to as a "non-common part." As a preliminary point, claims 7 and 17 have been canceled, rendering the rejection thereto moot. For the remaining claims, Applicants respectfully traverse this rejection.

Specifically, as expressly disclosed at page 30, line 21 to page 31, line 4 of the specification, the first extension portion 220 is removed from the first base plate 22, and the second extension portions 240 are removed from the second base plate 24, such that the

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remaining part of the biosensor comprising the first base plate 22 and the second base plate 24 is referred to as common part, while the first extension portion 220 and the second extension portions 240 are each referred to as the non-common part. As such, it is respectfully submitted that claims 3-10 and 17 are in compliance with the requirements of 35 U.S.C. § 112, 2nd paragraph. Nonetheless, in an effort to advance prosecution, claim 3 has been amended to recite "wherein said first base plate and or said second base plate each comprises has a shape having a part having a common shape part and a part having a non-common shape relative to the other base plate part, said non-common part having a specific shape corresponding to said specific substrate." Accordingly, for all of the foregoing reasons, it is respectfully requested that this rejection of claims 3-10 and 17 be withdrawn in view of the foregoing amendment.

V. The Rejection Of Claims 1, 2 and 11-14 Under 35 U.S.C. § 102

Claims 1, 2 and 11-14 are rejected under 35 U.S.C. § 102(e) as being anticipated by USP No. 6,616,819 to Liamos. Applicants respectfully traverse this rejection for at least the following reasons.

Claim 1 recites in-part that ... a first extension portion ... extends in a *length* direction of said first base plate from ... an *end* of said second base plate ..., and has ... part of said first lead exposed ..., and wherein ... a second extension portion ... extends in a *width* direction of said second base plate from ... an *end* of said first base plate ..., and has ... part of said second lead exposed

In the pending Office Action, the Examiner relies on Figs. 8A-8C of Liamos as allegedly disclosing the claimed invention. Specifically, the Examiner reads the substrate 540 and the working electrode 542 of Liamos as the respective claimed first base plate and first electrode,

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and the substrate 548 and the counter electrodes 550/552/554 of Liamos as the respective claimed second base plate and second electrode.

However, in such an interpretation, it is clear that the first substrate 540 of Liamos does not contain any extension that extends in the *length* direction from the *end* of the second substrate 548. Similarly, the second substrate 548 does not contain any extension that extends in the *width* direction from the *end* of the first substrate 540. This is evidenced by the fact that the first substrate 540 and the second substrate 548 of Liamos both have the *same shape*.

In direct contrast, the present invention utilizes the first base plate 22 comprising the first extension portion 220 that extends in a *length* direction of the first base plate 22 from the end of the second base plate 24 such that a part of the first lead 230 is exposed. Similarly, the present invention utilizes the second base plate 24 comprising the second extension portion 240 that extends in a *width* direction of the second base plate 24 from the end of the first base plate 22 such that a part of the second lead 250 is exposed.

Furthermore, it is asserted in the pending Office Action that the substrate 432 illustrated in Fig. 5A contains lengthwise extensions via the tabs 425' (see, page 4, last 4 lines of Office Action). However, as is apparent from Liamos, the substrate 432 and the substrate 434 both have the *same length*. As such, the substrate 432 illustrated in Fig. 5A of Liamos does not contain any lengthwise extension that extends from the *end* of the substrate 434 illustrated in Fig. 5B.

Moreover, the Examiner asserts that substrates 540 and 548 contain widthwise extensions at the electrode location. However, it is respectfully submitted that this interpretation still fails to arrive at the claimed invention, because when the first substrate 540, the spacer 544 and the

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second substrate 548 are assembled together, it is clear that the alleged widthwise extensions of the second substrate 548 are *not* exposed (i.e., exposed to outside), as required by claim 1.

With respect to claim 11, this claim, as amended, recites in-part a measuring apparatus comprising a sensor mounting *opening section* having a first sensor mounting segmental portion and a second sensor mounting segmental portion. In accordance with one exemplary embodiment of the present invention, the inlet of the space A (first sensor mounting segmental portion) is defined by the rectangular points b1, b2, b9, b10, c1, c2, c9 and c10 (see, Fig. 11), while the inlet of the space C (second sensor mounting segmental portion) is defined by the rectangular points a4, a5, a6, a7, b4, b5, b6 and b7. More specifically, the space A corresponds to the first base plate 22 comprising the first extension portion 220 in the mounting end portion 20, and has a size suitable for having such mounting end portion 20 of the first base plate 22 fitted thereto, whereas the space C corresponds to the second base plate 24 comprising the second extension portions 240 in the mounting end portion 20, and has a size suitable for having such end portion of the second base plate 24 fitted thereto (see, e.g., page 32, line 18 to page 33, line 19 of the specification).

However, as the connector 1500 of Liamos merely comprises a top cover 1510 and a bottom cover 1520, it is clear that the connector 1500 cannot be construed as the claimed opening section. In an event it is asserted that the slide area 1530 of Liamos corresponds to the claimed sensor mounting segmental opening section, it is important to note that the top portion of the slide area 1530 (see, Fig. 16A) for fitting the alleged first substrate thereto has the *same width* as the bottom portion of the slide area 1530 for fitting the alleged second substrate thereto.

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Also, as the alleged first sensor mounting segmental portion and second sensor mounting segmental portion are *not* part of (i.e., formed as) the slide area, it is respectfully submitted that the slide area does not *comprise* the contact leads 1444/1425/1443/1423.

Accordingly, as anticipation under 35 U.S.C. § 102 requires that each element of the claim in issue be found, either expressly described or under principles of inherency, in a single prior art reference, *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983), and at a minimum, Lliamos fails to disclose or suggest the foregoing claim elements, it is clear that Lliamos does not anticipate claim 1 or 11, or any of the claims dependent thereon.

VI. The Rejection Of Claim 11 Under 35 U.S.C. § 102

Claim 11 is rejected under 35 U.S.C § 102(b) as being anticipated by USP No. 5,096,669 to Lauks. Applicants respectfully traverse this rejection for at least the following reasons.

In the pending rejection, the Examiner alleges that because each of the top and bottom sensor plates of Lauks has a different width, the protrusions within the alleged sensor mounting portions must necessarily have a different width.

However, as a preliminary point, it is respectfully submitted that the logic set forth in the pending rejection in making the above conclusion is flawed, because the foregoing position appears to overlook and ignore the fact that the opening 360 of the reader 150 of Lauks as illustrated in Figs. 1 and 11 clearly has a single *uniform* width, even if the upper housing member 90 of the disposable device of Lauks does not contain additional notches 36/38 as shown in the lower housing member 12. At best, the inherency argument set forth in the rejection indirectly reflects the *possibility* of having an opening including segments of different

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width without demonstrating that the segments of the opening 360, if disclosed, MUST have different width.

Accordingly, as anticipation under 35 U.S.C. § 102 requires that each element of the claim in issue be found, either expressly described or under principles of inherency, in a single prior art reference, *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983), and at a minimum, Lauks fails to disclose or suggest the foregoing claim elements, it is clear that Lauks does not anticipate claim 11, or any of the claims dependent thereon.

VII. The Rejection Of Claim 11 Under 35 U.S.C. § 102

Claim 11 is rejected under 35 U.S.C § 102(b) as being anticipated by USP No. 6,071,391 Gotoh. Applicants respectfully traverse this rejection for at least the following reasons.

In the pending rejection, it is again asserted that because "the extension portions have different widths . . . , the corresponding portion would [inherently] require segments of different width."

However, it is respectfully submitted that the Examiner's interpretation departs from what is disclosed in Gotoh. Specifically, as expressly disclosed in Fig. 15 and at col. 15, lines 8-30 of Gotoh, the connector part 11 contains four input terminals 12/13/14a/14b. That is, the connector part 11 only contains a single uniform width, and Gotoh is completely silent with regard to two portions of the connector part 11, let alone disclose having different widths thereof. At best, Gotoh only discloses an opening having a single four-terminal connector part, and the Examiner's reconstruction indirectly reflects the *possibility* of having a connector part including segments of different width. However, as is well known, "inherency may not be established by probabilities or possibilities," *Scaltech Inc. v. Retec/Tetra*, 178 F.3d 1378 (Fed. Cir. 1999). In

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the instant case, even assuming *arguendo* that the connector part 11 of Gotoh can embody different segment widths, it is *not* necessary that the connector part 11 of Gotoh MUST have different widths.

Accordingly, as anticipation under 35 U.S.C. § 102 requires that each element of the claim in issue be found, either expressly described or under principles of inherency, in a single prior art reference, *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983), and at a minimum, Gotoh fails to disclose or suggest the foregoing claim elements, it is clear that Gotoh does not anticipate claim 11, or any of the claims dependent thereon.

VIII. The Rejection Of Claims 1, 3-5 and 7 Under 35 U.S.C. § 103

Claims 1, 3-5 and 7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over JP 09-159642 to Nagata in view of USP No. 5,320,732 to Nankai. In response, Applicants have canceled claim 7, without prejudice or disclaimer, rendering the rejection thereto moot. For the remaining claims, Applicants respectfully traverse this rejection for at least the following reasons.

In the pending rejection, the Examiner admits that Nagata does not disclose or suggest a second extension portion extending in a width direction from the second base plate from a position corresponding to an end of the first base plate, but alleges that Nankai discloses, in Fig. 1 and at col. 2, lines 6-24, the foregoing claim element.

However, contrary to the conclusion set forth in the pending rejection, the substrates 1b (alleged first base plate) and 1a (alleged second base plate) of Nagata have the *same* length (see, Fig. 1). That is, the substrate 1b of Nagata does not extend from the *end* of the substrate 1a in the lengthwise direction. Nankai, on the other hand, merely discloses a projection 11 for

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preventing the biosensor from being inserted backward into the device, wherein the projection 11 is a part of the base 1 comprising the working electrode 5, rather than a part of a second base comprising a counter or second electrode. Indeed, noting that the top layer of the biosensor of Nankai is merely a cover 9, Nankai is silent with regard to providing a second base, let alone disclose a second extension portion extending from such a second base comprising a second electrode.

It should be recognized that the fact that the prior art could be modified so as to result in the combination defined by the claims at bar would not have made the modification obvious unless the prior art suggests the desirability of the modification. *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986).

Moreover, recognizing after the fact that such a modification would provide an improvement or advantage, without suggestion thereof by the prior art, rather than dictating a conclusion of obviousness, is an indication of improper application of hindsight considerations. Simplicity and hindsight are not proper criteria for resolving obviousness. *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967).

It is only Applicants' disclosure that discloses the claimed biosensor. Neither Nagata nor Nankai disclose or suggest such a biosensor. Thus, the only motivation of record for the proposed modification of the biosensor of Nagata to arrive at the claimed invention is found in Applicants' disclosure which, of course, may not properly be relied upon to support the ultimate legal conclusion of obviousness under 35 U.S.C. § 103. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 2271 USPQ2d 1593 (Fed. Cir. 1987).

Thus, as each and every limitation must be either disclosed or suggested by the cited prior art in order to establish a *prima facie* case of obviousness (see, M.P.E.P. § 2143.03), and Nagata

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and Nankai, alone or in combination, fail to do so, it is respectfully submitted that claim 1 is patentable over the cited prior art.

IX. The Rejection Of Claims 1-10, 12-14 and 17 Under 35 U.S.C. § 103

Claims 1-10, 12-14 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gotoh and Lauks, and further in view of USP No. 6,495,104 to Unno. In response, Applicants have canceled claim 7, without prejudice or disclaimer, rendering the rejection thereto moot. For the remaining claims, Applicants respectfully traverse this rejection for at least the following reasons.

In the pending rejection, the Examiner asserts that Gotoh discloses a first base plate, but admits that Gotoh does not disclose or suggest a second base plate having extensions in the width direction from positions corresponding to the ends of the first base plate. Lauks and Unno are relied upon to meet the claimed invention.

As a preliminary matter, it is respectfully submitted that the Examiner's admitted statement is in conflict with the allegation that Gotoh discloses the claimed first base plate. Specifically, claim 1 recites in-part that ... a first extension portion ... extends in a *length* direction of said first base plate from ... an *end* of said *second base plate*. However, absent a second base having widthwise extensions, it is not entirely understood how the base 1 of Gotoh can be construed as the claimed first base plate, given that the claimed first base plate and the second base plate are *inter-related*.

Even assuming *arguendo* that the Examiner's interpretation is proper, it is important to note that the base 1 and the base 1' of Gotoh have the *same* length, and the difference in shape between the base 1 and the base 1' relies on the extra width extended by the electrode lead 3 in the *widthwise* direction, rather than in the *lengthwise* direction. Most importantly, the notches

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36/38 of the lower housing member 12 of Lauks also extend in the *same* manner as that of portion extended by the electrode lead 3 of Gotoh. That is, the Examiner's proposed combination still fails to arrive at the claimed invention, because the electrode lead 3 (alleged first extension portion) of Gotoh and the notches 36/39 (alleged second extension portion) of Lauks can only be interpreted as *both* extending in the widthwise direction, or as *both* extending in the lengthwise direction. Accordingly, the proposed combination would *not* result in having an extension extended in the *length* direction and another extension extended in the *width* direction.

Furthermore, it is respectfully submitted that if Gotoh is to be modified to practice the teachings of Lauks in the manner alleged by the Examiner, Gotoh would necessarily be modified to replace the base 1' with the lower housing member 12 of Lauks having the notches 36/38, which would render Gotoh inoperable for its intended purpose, because Gotoh is completely silent with regard to adding such notches (let alone disclose a method thereof) to the base 1'. It is clearly improper for the Examiner to simply pick and choose selected elements of the prior art to reconstruct the claimed invention. It is respectfully submitted that the proposed combination is based *solely* on improper hindsight reasoning, whereby the Examiner selected bits and pieces of the claimed invention from plural references and used *only* Applicants' specification as a guide to reconstruct the claimed invention. Therefore, the proposed combination fails to establish *prima facie* obviousness of the rejected claims.

Furthermore, the rejection has not provided any requisite objective evidence *from the cited prior art* in supporting the argument that the portion extended by the electrode lead 3 of Gotoh necessarily extends in a *length* direction of the base 1 from the *end* of the lower housing member 12 of Lauks, or that the notches 36/38 of Lauks necessarily extend in a *width* direction

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of the lower housing member 12 from an *end* of the base 1. This is further supported by the fact that neither Gotoh nor Lauks express any specific dimension such that the inter-relationship between alleged first extension portion and the alleged second extension portion can readily be determined. Absent this teaching, it is respectfully submitted that the proposed modification is improper. Therefore, for at least these reasons, the proposed modification fails to establish *prima facie* obviousness of the pending claims.

Thus, as each and every limitation must be either disclosed or suggested by the cited prior art in order to establish a *prima facie* case of obviousness (see, M.P.E.P. § 2143.03), and Gotoh and Lauks fail to do so, it is respectfully submitted that claim 1 is patentable over the cited prior art.

X. All Dependent Claims Are Allowable Because The Independent Claims From Which They Depend Are Allowable

Under Federal Circuit guidelines, a dependent claim is nonobvious if the independent claim upon which it depends is allowable because all the limitations of the independent claim are contained in the dependent claims, *Hartness International Inc. v. Simplimatic Engineering Co.*, 819 F.2d at 1100, 1108 (Fed. Cir. 1987). Accordingly, as independent claims 1 and 11 are patentable for the reasons set forth above, it is respectfully submitted that all claims dependent thereon are also in condition for allowance.

XI. Conclusion

Accordingly, it is urged that the application is in condition for allowance, an indication of which is respectfully solicited.

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If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicants' attorney at the telephone number shown below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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